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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

7590 10/23/2002

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,521

Applicant(s)

GIRTON ET AL.

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 5-10, and 17-20, drawn to an endoprosthesis, classified in class 623, subclass 1.13
 - II. Claims 4 and 11-16, drawn to a method of making a porous polymer, classified in class 524, subclass 903.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I. and II. are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the endoprosthesis may be made by another process such as laser removal, punching or cutting pores, salt leaching, or polymer's other than siloxane extracted. The method of making a polymer may form polymers that may be used as products other than endoprostheses, such as circuit boards, surgical apparel or cables.
3. Because these inventions are distinct for the reasons given above and the search required for Group II. is not required for Group I., restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mark Baron (reg. No. 46,150) on October 18, 2002 a provisional election was made with traverse to prosecute the invention of Group I., claims 1-3, 5-10, and 17-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4 and 11-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

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inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract is too short in length, it is suggested to lengthen the abstract to 50 words and further description. Also, the phrase "is disclosed" in line 1, is legal terminology, and should be deleted.

Drawings

2. Figure 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 11, 13. A proposed drawing

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correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 5-10 and 17-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 13-16 of copending Application No. 09/704,494. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Zilla et al. (WO/00/30564, cited by applicant in IDS). Zilla discloses a medical device or vascular graft (pg.4, lines 12-13) comprising a tubular extrudate (pg.11, lines 1-5) comprising a PTFE matrix (pg.5, lines 15-17) having domains of an extractable polymeric material (pg.4, lines 3-4), wherein subjecting the extrudate is

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exposed to a dissolving medium or degrading temperature to extract a portion of the polymer, forming pores (pg.6, lines 21-23).

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell (WO 87/02996, cited by applicant in IDS). Mitchell discloses a medical device or vascular graft (pg.2, lines 19-20) comprising a tubular extrudate comprising a PTFE matrix having domains of an extractable polymeric material, wherein subjecting the extrudate is exposed to a dissolving medium or degrading temperature to extract a portion of the polymer, forming pores (tables 4, 5; pg.13, lines 1-11).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zilla in view of Dereume et al. (USPN 5,639,278). Zilla discloses a medical device (pg.4, lines 12-13) comprising a tubular extrudate, commonly known as a graft (pg.11, lines 1-5) comprising a PTFE matrix (pg.5, lines 15-17) having domains of an extractable polymeric material (pg.4, lines 3-4). Zilla does not teach however, a stent combined with a graft. Dereume teaches combining an axially positioned stent (22) combined with a graft (23 or 24), in order to provide increased support by the stent, enhanced tissue ingrowth by the graft, and means to cover an aneurysm in an artery or vein (col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent with a graft, with Mitchell's type of extruded graft made of porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an aneurysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

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11. Claims 5-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (WO 87/02996, cited by applicant in IDS) in view of Dereume et al. (UPSN 5,639,278). Referring to claims 5-7, 17, and 19-20, Mitchell discloses an endoprosthesis for replacing arteries and veins, commonly known in the art as a graft (pg.2, lines 19-20). Mitchell discloses an endoprosthesis that is a non-expanded (pg.19, lines 4-7) porous PTFE material. Mitchell discloses a method of forming the endoprosthesis by providing an IPN of siloxane and PTFE (pg.13, lines 1-11, pg.25, 26, 28) and removing (extracting) the siloxane (table 5) from the IPN, leaving a porous polytetrafluoroethylene (table 4). Mitchell does not disclose however, using the endoprosthesis to cover a stent surface. Dereume teaches combining a radially expandable stent (22) in between two radially expandable grafts (23, 24), in order to provide increased support, enhanced tissue ingrowth, and means to cover an aneurysm in an artery or vein (col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent in between two grafts, with Mitchell's type of graft made of non-expanded porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an aneurysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

Referring to claims 8-10, Mitchell discloses a removal of siloxane by chemicals extraction such as toluene (ingredients table 1), or by heat extraction (pg.1, lines 23-25) above a temperature of 300°C (pg.22, lines 1-10).

Referring to claim 18, Mitchell discloses both a non-expanded porous PTFE endoprosthesis, and an expanded porous PTFE, and teaches that nodes and fibrils are formed upon expansion (pg.11, lines 23-24), and because nodes and fibrils are absent before expansion, it is inherent that nodes and fibrils are absent in the non-expanded porous PTFE.

A note to the applicant: claims 5 and 8-10 are product by process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

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product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

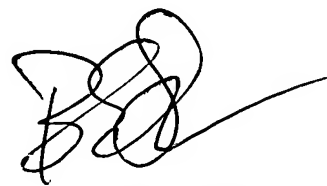
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

October 18, 2002



BRUCE SNOW
PRIMARY EXAMINER